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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,525	06/19/2006	Giovanni Mogna	BUGS-39568	7210
116 7590 03/27/2008 PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108				
EXAMINER ARIANE, KADE				
ART UNIT		PAPER NUMBER		
1651				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/566,525

## Applicant(s)

MOGNA ET AL.

## Examiner

KADE ARIANI

## Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 6-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 6-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- \_\_\_\_\_ Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- \_\_\_\_\_ Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### ***DETAILED ACTION***

The amendment filed on December 21, 2007, has been received and entered.

Claims 3-5 have been canceled.

Claims 1, 2, 6-13 are pending in this application and were examined on their merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "wherein the individual brushes are 5" in claim 12 is indefinite, because it is unclear exactly what applicant intends.

Claim 13 recites the limitation "the biopsy channel is washed...". There is no antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claim 8 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101, is withdrawn due to applicant amendments to the claims filed on 12/21/07.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-10 under 35 U.S.C. 102(b) as being anticipated by Alander et al. (in IDS, Letters in Applied Microbiology, 1997, Vol. 24, p.361-364), is withdrawn due to Applicants amendments to the claims filed on 12/21/07.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alander et al. (in IDS, Letters in Applied Microbiology, 1997, Vol. 24, p.361-364) in view of Reuter, G., (Current Issues in Intestinal Microbiology, 2001, Vol. 2, No. 2, p.43-53) and further in view of Patwari et al. (Indian J Pediatr, 2001, Vol. 68, No.6, p.515-518).

Claims 1, 2, 6-13 are drawn to a process for collecting bacteria adhered to the intestinal wall comprising the steps of carrying out a colonoscopy with brushes adapted for cell collection, and collecting bacteria adhered to the intestinal wall, wherein the collection is carried out in various segments of the bowels several intestine segments of individual by means of individual brushes, walls of the distal ileum, right, transverse colon and left colon, culturing and analyzing the collected strains, isolating bacterial strains, and a composition comprising probiotic bacteria strains.

Alander et al. teach a process for collecting bacteria adhered to the intestinal wall of a subject, by colonoscopy through brushes, collection is carried out in several intestine segments of individual, walls of ascending, transverse, and descending colon, culturing and analyzing the collected strains, and isolating bacterial strains, and a composition comprising probiotic bacteria strains (see Abstract, Introduction and p.362, column 1 and column 2, "Colonoscopy & biopsies" and "Sampling & cultivation").

Applicant's arguments filed on 12/21/07 have been fully considered but they are not persuasive.

Applicant argues that Alander et al. do not teach that individual brushes are used to biopsy the tissue containing the bacteria from separate segments of the small intestine, thus, one brush contains bacteria from only that one specific segment.

Applicant argues that there is nothing in Alander et al. to suggest that to isolate and collect different bacteria from different tissues.

Alander et al. is silent about wherein the collection is carried out in various segments by means of individual brushes. However, a person of ordinary skill in the art would have known to change the brush while collecting samples from different segments of the intestinal wall to prevent contamination. Also further motivation is in Patwari et al. who teach endoscopic brush cytology (EBC), and teach care must be taken to minimize contamination while performing EBC by thoroughly cleaning the cytology brush and the tip to minimize contamination (Abstract, and p.516 Material & Methods).

Therefore, it would have been obvious to one of ordinary skill in the art to use individual brushes while collecting samples in the method as taught by Alander et al. in order to provide a process for collecting bacteria adhered to the intestinal wall. The motivation would be to minimize the contamination.

Further motivation to isolate and collect different bacteria from different tissues, are in Reuter who teaches Lactobacillus and bifidobacterial cultures are increasingly used as probiotics in pharmaceuticals and in food. The selection of strains is performed often for technological rather than for microecological reasons. Detailed reports about species and strains composition of the microorganisms in the intestinal microflora of man are rare (Abstract). Reuter teaches, the gastro intestinal microflora is a very

complex community, within the gastrointestinal tract, different habitats have to be recognized, e.g. mouth, stomach small intestine, especially large jejunum and ileum, large intestine and rectum. The balance is influenced primarily by the host's individuality this means interpersonal variation exists (p. 43, Introduction 2<sup>nd</sup> column 2<sup>nd</sup> paragraph, and p.49 Table 6.). Reuter further teaches the selection of suitable species or strains as probiotics culture is a very critical step (p.44, 1<sup>st</sup> column, last paragraph). Reuter teaches strains from distal ileum (p.46, 2<sup>nd</sup> column 1<sup>st</sup> paragraph lines 2-5), and teaches it can be concluded that in the small intestine there might exist a more defined individual character of indigenous flora than in the colon (p.48 2<sup>nd</sup> column 3<sup>rd</sup> paragraph).

Therefore, it would have been obvious to one of ordinary skill in the art to collect samples from distal ileum, and segments of colon in the method as taught by Alander et al. in order to provide a process for collecting bacteria adhered to the intestinal wall. The motivation as taught by Reuter would be to provide a detailed report about species and strains composition of the indigenous intestinal microflora.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/  
Primary Examiner, Art Unit 1651

Kade Ariani  
Examiner  
Art Unit 1651

